

**U.S.S.N. 10/071,620  
Gholam-Reza Zadno-Azizi, et al  
PRELIMINARY AMENDMENT**

The frame is to be capable of two states, an insertion state and an anchoring state. The anchoring state is larger than the insertion state by the laterally extending resilient elements being outward of the insertion position of these elements when they are in the anchor state.

**Please replace the paragraph on page 11, lines 12-23, with the following:**

Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device which has longitudinally extending elements that are of spring material. The elements are bent such that the frame is radially constricted. The size of the sheath's inner diameter is such that the spring elements are not bent to the point that they exceed the elastic limit. A ram 90 extends into the sheath 88 to force the fluid flow control device from the end of the sheath. As the device is released from the sheath 88, it will naturally expand to the anchored state. This same mechanism may be employed with any of the devices for placement regardless of whether the mechanism for expansion is deformation, heat recovery or resilience. Naturally, the ram 90 can accommodate a heating element or balloon mechanism depending upon the appropriate need.

**Please replace the paragraph on page 12, lines 8-16, with the following:**

Considering the use of these devices, the thresholds are selected with the appropriate pressures in mind. With incontinence, the threshold pressure is high enough to prevent leakage as normal pressure builds in the bladder. When the bladder



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Gholam-Reza Zadno-Azizi, et al.  
Serial No.: 10/071,620  
Filed: February 8, 2002  
For: **BODY FLUID FLOW CONTROL DEVICE**  
Art Unit: 3738  
Examiner: Unassigned

**ATTACHMENT TO PRELIMINARY AMENDMENT  
(MARKED-UP PARAGRAPHS)**

**IN THE SPECIFICATION**

**Please amend the paragraph on page 2, lines 2-6, as follows:**

Native valves are also found in cardiovascular systems. In veins, native venous valves promote one-way flow toward the heart from the periphery. Diseases exist such as venous thrombosis and thrombophlebitis which can render native venous valves incompetent, resulting in edema. Replacement of these [artificial] native valves with artificial ones could provide substantial health benefits.

**Please amend the paragraph beginning on page 9, line 21, through page 10, line 1, as follows:**

The frame is to be capable of two states, an insertion state and an anchoring state. The anchoring state is larger than the insertion state by the laterally extending resilient elements being [outwardly] outward of the insertion position of these elements when they are in the anchor state.

**Please amend the paragraph on page 11, lines 12-23, as follows:**

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**Marked up attachment to Preliminary Amendment**

Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device which has longitudinally extending elements that are of spring material. The elements are bent such that the frame is radially constricted. The size of the [sheath] sheath's inner diameter is such that the spring elements are not bent to the point that they exceed the elastic limit. A ram 90 extends into the sheath 88 to force the fluid flow control device from the end of the sheath. As the device is released from the sheath 88, it will naturally expand to the anchored state. This same mechanism may be employed with any of the devices for placement regardless of whether the mechanism for expansion is deformation, heat recovery or resilience. Naturally, the ram 90 can accommodate a heating element or balloon mechanism depending upon the appropriate need.

**Please amend the paragraph on page 12, lines 8-16, as follows:**

Considering the use of these devices, the thresholds are selected with the appropriate pressures in mind. With incontinence, the threshold pressure is high enough to prevent leakage as normal pressure builds in the bladder. When the bladder is to be voided, abdominal pressure is used. The threshold pressure is also low enough that the abdominal pressure will overcome the resistance and allow flow. Where placement is in the cardiovascular system, minimum resistance to flow in one direction may be designed into the valve. In this application, however, substantial resistance to